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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,091	XU ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/27/05; 11/16/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The instant application contains some grammatical errors and needs some editing to remove these errors. See in particular the last sentence of the Abstract.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure. Applicant is also respectfully requested to edit the instant disclosure to correct the obvious errors in English usage and other grammatical errors.

The oath or declaration may be defective. A new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying this application by its Serial Number and filing date is required. See MPEP 602.01 and 602.02. The oath or declaration is defective because:

The instant declaration identifies three inventors, a result different that the instant bibliographic data sheet wherein only two inventors have been identified. There is presently no "application data sheet" in the instant electronic file. Applicant is respectfully requested to provide any additional information necessary to determine the correct inventorship.

No claims have been cancelled, no claims have been amended, the disclosure has **not** been amended, and no new claims have been added as of the date of this Office action. Two Information Disclosure Statements (2 IDSs) filed September 27, 2005 and November 16, 2005 have been received with all cited references and made of record.

Claims **1-7** remain in the case.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims **1-4 and 7** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Applicant is referred to claims **1-4 and 7** wherein the term "use" is found at line 1. Examiner suggests amendment of the noted claims to conform to US practice.

Claims **1-7** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the administration of N-acetyl-D-glucosamine to inhibit the negative effects of poisoning by methanol ingestion, poisoning by the ingestion of the insecticide "Rogor," (See PTO-892 ref. R wherein this substance is identified) or poisoning by ingestion of a source of lead, does not reasonably provide enablement for inhibiting any other adverse effect caused by the administration of any other class of substance including any compound generally recognized as a "drug." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Note: The instant rejection is drafted broadly because the term "use" in the context of claims **1-4** may be read to encompass both method-of-treatment subject matter and how-to-make-pharmaceutical-compositions subject matter. In light of the art rejections wherein disclosure of how to make pharmaceutical compositions is noted, narrowing of the instant claims by amendment is likely to produce at least a similar narrowing of the scope of this rejection.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8

USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims define a method of medical treatment wherein N-acetyl-D-glucosamine is administered to treat "organ lesions" caused by administration of "toxicants and drugs," terminology covering a vast array of disease conditions caused by contact of a host with vast arrays of "toxicants and[/or] drugs." The breadth of the claims is deemed to be excessively broad because the specific examples are limited to the treatment of poisoning by methanol, of poisoning by an insecticide, or of poisoning by a lead compound.

B. The nature of the invention: The invention is directed to the administration of N-acetyl-D-glucosamine to effect treatment of "organ lesions" caused by contact of a host with "toxicants or drugs."

C. The state of the prior art: N-Acetyl-D-glucosamine-containing pharmaceutical compositions are disclosed to be an effective treatment of inflammatory bowel disease (IBD) and also psoriatic skin lesions in **Burton et al. '962** (PTO-1449 ref. **8**) at column 7, lines 17-18. **Glucogenics '929** (PTO-1449 ref. **4**) also discloses the administration of N-acetyl-D-glucosamine-containing pharmaceutical compositions to treat IBD. The noted references each also disclose how to make N-acetyl-D-glucosamine-containing pharmaceutical compositions. A separate search of the literature on-line (CAPLUS) did not produce any additional citations relevant to the instant claimed subject matter.

D. The level of one of ordinary skill: One of ordinary skill would be expected to have knowledge of how to apply medical treatments for the reversal of poisoning by chemicals including alcohol, pesticides and heavy metals.

E. The level of predictability in the art: In light of the very small number of prior art references cited herein and the lack of any prior teaching in this art area, the extrapolation of the instant claimed method to the treatment of the effects of additional poisons beyond the three exemplified is deemed to be highly unpredictable.

F. The amount of direction provided by the applicant: The instant disclosure only provides three examples of the effective treatment of poisoning in small mammals.

G. The existence of working examples: This subject is summarized in the preceding paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the effects of only three poisons (toxicants) has been shown to be effective inhibited in a population of small mammalian test subjects, and no poisoning by any "drug" has been shown to be possible by administration of N-acetyl-D-glucosamine to a host in need thereof.

Claims **1-7** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **1, 4 and 5** the term "organ lesions caused by toxicants and drugs" is unclear because the included terms "organ lesions," "toxicants," and "drugs" are not adequately further defined as to metes and bounds in the claims. The noted terms are generic and therefore do not, standing alone, define the particular "organ" diseases or dysfunctions, the particular "toxicants," or the particular "drugs" intended to be included within the scope of the instant claims. The claims do not define the particular undesired effects/diseases or "organ lesions" caused by contacting a host with a particular toxicant or a particular drug.

Claims **1 and 5** are incomplete because neither of the noted claims do specifies a --host in need thereof --. This rejection assumes that both claims are directed at least in part to a method of treatment.

In claims **1 and 4** the term "organ lesions caused by toxicants and drugs" is a method of treatment limitation, and therefore lacks any patentable weight in what appear to be method of making claims. Deletion is respectfully requested.

In claim **1** the term "medicament" is no longer commonly present in patent claims directed to pharmaceutical compositions. This term has been replaced by the term -- pharmaceutical composition --, a term defined as -- a mixture of at least one active ingredient and a pharmaceutically acceptable carrier --. Examiner also notes that the term "pharmaceutical composition" is present in instant claim **5** but is incompletely defined therein because claim **5** has not also included the term -- a pharmaceutically acceptable carrier --. This

missing part of the definition of "pharmaceutical composition" means that at present claims **6 and 7** lack proper antecedent basis in claim **5**, a problem easily soluble by adding the missing term to claim **5** as suggested above.

Claims **1 and 4** appear to be possible equivalents or duplicates of claim **5**. Upon amendment of "use" claims, applicant is respectfully requested to avoid generating duplicate claims.

In claims **1, 4 and 5** the term "toxicants and drugs" implies that the instant method of treatment is effective in treating hosts simultaneously exposed to multiple different substances when the instant examples are restricted to single poisons tested one at a time. Examiner respectfully suggests that the instant claims need to be amended to make the noted term read such as -- selected from the groups consisting of individual toxicants and individual drugs -- or the like, to make plain that the treatment only applies to the inhibition of the adverse effect of a single substance on a single host.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **1-4** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Burton et al. '962** (PTO-1449 ref. **8**)

Applicant is referred to the '962 reference at column 6, lines 58-62.wherein the preparation of a pharmaceutical composition containing N-acetyl-D-glucosamine has been disclosed, thereby anticipating the instant claims.

See also **Glucogenics '929** (PTO-1449 ref. **4**) wherein suppositories containing N-acetyl-D-glucosamine are also disclosed along with how to make same.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-4** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Burton et al. '962** (PTO-1449 ref. **8**) in view of **Glucogenics '929** (PTO-1449 ref. **4**).

The instant claims are directed to a process of making pharmaceutical compositions wherein N-acetyl-D-glucosamine is the active ingredient.

Burton et al. '962 discloses at at column 6, lines 58-62.the preparation of a pharmaceutical composition containing N-acetyl-D-glucosamine.

Burton et al. '962 does not expressly disclose any other combination of ingredients leading to a different N-acetyl-D-glucosamine-containing pharmaceutical composition.

Glucogenics '929 discloses at page 6, line 23 to page 9, line 24, a vast array of different alternative pharmaceutical compositions wherein the active ingredient is N-acetyl-D-glucosamine. This disclosure includes both generic and specific pharmacetuical compositions.

Glucogenics '929 does not expressly disclose any pharmaceutical composition wherein the instant method of treatment limitation has been specified.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare any one of the vast array of different pharmaceutical compositions taught either generically or specifically by either **Burton et al. '962** or **Glucogenics '929**. In addition it would have been obvious to a person of ordinary skill in the art at the time the invention was made to elect any one of the pharmaceutical compositions taught by either of **Burton et al. '962** or **Glucogenics '929** as a part of routine experimentation.

One having ordinary skill in the art would have been motivated to combine these references because both references teach one or more exmaples of the preparation of pharmaceutical compositions wherein N-acetyl-D-glucosamine is the active ingredient.

Therefore, the instant claimed pharmaceutical compositions would have been obvious to one of ordinary skill in the art having the above-cited references before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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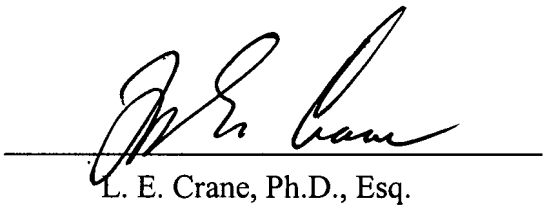

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